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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,857	11/25/2003	Fred H. Burbank	R0368-03200	6931

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EXAMINER

ADAMS, AMANDA S

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.		Applicant(s)	
	10/721,857		BURBANK ET AL.	
	Examiner		Art Unit	
	Amanda Adams		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 10/18/06, 10/19/06, 9/28/06, 6/14/06, 10/7/05,
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to a device, classified in class 600, subclass 201.
- II. Claims 24-31, drawn to a method, classified in class 606, subclass 193.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case The product as claimed can be used for other processes, such as distracting two layers of tissue from each other in another part of the body, such as the upper abdominal area.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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5. Claims 1-7 and 10-31 are generic to the following disclosed patentably distinct species:

- a. Species A: drawn to Figure 1
- b. Species B: drawn to Figure 6.

The species are independent or distinct because they rely on different mechanisms for the movement of the occlusion element. Figure 1 displays an embodiment wherein the movement is effected by a screw mechanism, and figure 6 displays an embodiment wherein movement is effected by a hydraulic system. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. During a telephone conversation with Ed Lynch on March 14, 2007, a provisional election was made with traverse to prosecute the invention of Group I and Species A, claims 1-7 and 9-23. Affirmation of this election must be made by applicant in replying

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to this Office action. Claims 8 and 24-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the occlusion element" is unclear as to whether the first or the second occlusion element is being referred to.

9. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the occluding element" is unclear as to whether the first or the second occluding element is being referred to.

10. Claim 14 recites the limitation "the receiving recesses" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 16 recites the limitation "the blood flow sensor" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

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12. Claim 17 recites the limitation "the Doppler crystal" in line 1. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 18 recites the limitation "the Doppler crystal" in line 1. There is insufficient antecedent basis for this limitation in the claim.

14. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the occluding element" is unclear as to whether the first or the second occluding element is being referred to.

15. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the occluding member" is unclear as to whether the first or the second occluding member is being referred to.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-7, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schifano (US 5,591,173).

18. Regarding claim 1, Schifano discloses the invention substantially as claimed including a first occluding member which has a first elongated shaft, which has a first

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operative proximal shaft section configured to extend out of the patient during treatment (fig. 1 [11]), which has a first distal shaft section with a first pressure applying occluding element secured to the first distal shaft section ([24]) and which has a first mechanism to adjust the orientation or the location of at least part of the occluding element with respect to the first distal shaft section (compare figs. 4 and 5 [22]); a second occluding member which has a second elongated shaft, which has a second operative proximal shaft section configured to extend out of the patient during treatment ([12]) and which has a second distal shaft section with a second pressure applying occluding element secured to the second distal shaft section ([24] or [26]. Depending on which figure is being considered); and a connection between the first and second occluding members which is configured to adjust spacing between the first and second occluding elements to press the pressure applying elements against the patient's vaginal wall to occlude underlying uterine arteries ([13]).

19. Regarding claim 2, Schifano discloses the second occluding member has a second mechanism to adjust the orientation or the location of at least part of the second occluding element with respect to the second distal shaft section (figs. 4 and 5).

20. Regarding claim 3, Schifano discloses the connection between the first and second occluding members is a pivotal connection (figs. 4 and 5 [13]).

21. Regarding claim 4, Schifano discloses each of the proximal shaft sections of the occluding members include a finger engaging grip ([14]).

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22. Regarding claim 5, Schifano discloses at least part of the first occlusion element is configured for positional adjustment in-line with the distal shaft section (figs. 4 and 5 [20] and [24]).

23. Regarding claim 6, Schifano discloses at least part of the first occlusion element is configured for rotation within a plane at or near the distal shaft section (figs. 4 and 5).

24. Regarding claim 7, Schifano discloses at least part of the first occlusion element is configured to extend radially away from the distal shaft section (figs. 1, 4, 5).

25. Regarding claims 10 and 11, Schifano discloses that the occluding element includes an occlusion bar with a pressure applying surface (fig. 1 [26]), and that the occlusion bar has a pair of legs which extend from a surface opposite to the pressure applying surface ([23]).

26. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Santilli (US 6,610,074).

27. Santilli discloses the invention substantially as claimed including a first occluding member which has a first elongated shaft, which has a first operative proximal shaft section configured to extend out of the patient during treatment (figs. 8 and 9 [132]), which has a first distal shaft section with a first pressure applying occluding element secured to the first distal shaft section (fig. 9 [100]) and which has a first mechanism to adjust the orientation or the location of at least part of the occluding element with respect to the first distal shaft section (fig. 9 [118] and [116]); a second occluding member which has a second elongated shaft, which has a second operative proximal shaft section configured to extend out of the patient during treatment (figs. 8 and 9

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[122]) and which has a second distal shaft section with a second pressure applying occluding element secured to the second distal shaft section ([98]); and a connection between the first and second occluding members which is configured to adjust spacing between the first and second occluding elements to press the pressure applying elements against the patient's vaginal wall to occlude underlying uterine arteries (fig. 9).

28. Regarding claim 9, Santilli discloses the movement of the occlusion element is effected by a screw mechanism (fig. 9 [110]).

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (US 5,591,173).

31. Regarding claims 19 and 20, Schifano fails to disclose the angular orientation that the occluding element is oriented at with respect to the distal shaft section. However, the occluding element [24] is capable of being adjusted to an orientation of from about 90 degrees to about 180 degrees. Therefore it would have been obvious for the occluding element to be adjustable through this range of angles as well as from about 135 degrees to about 175 degrees.

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32. Regarding claim 21, Schifano fails to particularly disclose that the occluding member is displaced a distance of up to about one inch from the distal shaft section. However, it would have been obvious to displace the occluding member a distance of up to about one inch from the distal shaft section in order to make the device of a sufficient size to be used to occlude uterine arteries. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

33. Regarding claim 23, Schifano discloses the occluding element is rotated about a longitudinal axis of about 90degrees to about 180 degrees (figs. 4 and 5; the claim limitation does not specify the orientation of the longitudinal axis).

34. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (5,591,173) in view of Fogarty et al (US 6,293,954).

35. Regarding claim 12, Schifano discloses the invention substantially as claimed except for failing to disclose that the occlusion element has a pair of arms with recesses configured to receive legs extending from the occlusion bar. However, Fogarty teaches a device similar in design wherein the occlusion bars each have a leg with a recess to receive an arm of the occlusion element (fig. 1). Replacing the nut and bolt attachment mechanism of Schifano with the recesses of Fogarty would not change the function of the device, therefore it would have been obvious to substitute the arm, leg, and recess of Fogarty for the nut and bolt of Schifano. Further, it would have been obvious to rearrange the recessed attachment of Fogarty such that the recess is located in the arm

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instead of the leg, as this also causes no change in function to the device. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

36. Regarding claims 13 and 14, Schifano further discloses that the legs of the occlusion bar are biased away from the distal shaft section (fig. 1 [23]) and that the legs are biased by springs located in receiving recesses (fig. 2 spring [22] terminates in receiving recess defined as the space surrounded by three sides of [24]).

37. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (5,591,173) in view of Hossack et al (US 6,045,508).

38. Schifano discloses the invention substantially as claimed above but fails to disclose a blood flow sensor. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51). Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Schifano, in order to determine when the blood flow has been successfully occluded. It is also old and well-known in the art to have bloodflow sensors in occlusion devices. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the portion that is occluded can be measured.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-

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5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 3/21/07


GLENN K. DAWSON
PRIMARY EXAMINER